

## REALLOCATING INFLUENZA VACCINE

Public health departments and health care providers and institutions that consider reallocating influenza vaccine should be aware of the following FDA-related information.

Under Section 503(c)(3)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a health care entity may sell, purchase or trade (or offer to do the same with) influenza vaccine to alleviate a shortage if there is a reasonable basis to conclude that a shortage of influenza vaccine exists or will actually occur. A "shortage" includes a temporary shortage arising from delays in or interruptions of regular distribution schedules. Health care entities that experience a shortage or have a reasonable basis to conclude that they will experience a shortage, which would constitute an "emergency medical reason" for redistributing influenza vaccine under section 503(c)(3)(B)(iv) of the FD&C Act, may obtain influenza vaccine from other health care entities to the extent necessary to alleviate or prevent the shortage. Health care entities should keep in mind, however, that "emergency medical reasons" for redistributing influenza vaccine do not include "regular and systematic sales to licensed practitioners . . ." (21 C.F.R. 203.3(m)). Such sales would include agreements that hospitals will resell influenza vaccine to doctors in pre-set amounts, even though those doctors neither received a communication from their distributors that their vaccine delivery will be delayed, nor have any other reason to believe that they will not receive the influenza vaccine they ordered on time.

When redistribution occurs, the hospital or health care entity that is redistributing influenza vaccine should document and maintain the following information:

- \* vaccine brand name
- \* manufacturer and distributor
- \* lot number
- \* number of doses transferred
- \* recipient's name and address

In any such redistribution, the influenza vaccine and its transfer must comply with FDA's current good manufacturing requirements. Information on proper handling, storage, and shipping can be found at [http://www.cdc.gov/nip/publications/vac\\_mgt\\_book.htm#flu](http://www.cdc.gov/nip/publications/vac_mgt_book.htm#flu) .